



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

17/ Appeal
Brief (3)
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In re Application of:

Miri Seiberg et al

Serial No. 09/621,565

Filed: July 21, 2000

Attorney Docket No.: JBP 510

Examiner: Blessing Fubara

Art Unit: 1615

REGULATING HAIR GROWTH, HAIR
FOLLICLE AND HAIR SHAFT SIZE
AND HAIR PIGMENTATION

Be
12-4-02

APPEAL BRIEF

Box AF
Assistant Commissioner for Patents
and Trademarks
Washington, D.C. 20231

Dear Sir:

The above-identified patent application comes before the United States Patent and Trademark Office Board of Appeals and Interferences from the Final Rejection of Claims 1-22 by the Examiner in an Official Action mailed May 21, 2002. Pursuant to the Notice of Appeal filed September 23, 2002, set forth below is the Appellant's Brief due no later than November 21, 2002. Two additional copies of this Brief are enclosed. A check in the amount of Three Hundred and Twenty Dollars (\$320.00) is enclosed in payment of the fee under 37 C.F.R. § 1.17(c).

Additionally, Appellant is simultaneously filing a Request for Oral Hearing Before the Board of Patent Appeals and Interferences ("Request") in this Appeal. A check in the amount of Two Hundred and Eighty Dollars (\$280.00) is enclosed in payment of the fee under 37 C.F.R. § 1.17(d) with the Request.

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The Commissioner is hereby authorized to charge any fees or credit any overpayment, to Deposit Account 18-0586 during the entire pendency of this appeal.

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I. Real Party In Interest:

The real party in interest in the above-captioned application is Johnson & Johnson Consumer Companies, Inc. ("Appellant"), a corporation organized and existing under the laws of the State of New Jersey, and having a place of business at 199 Grandview Road, Skillman, New Jersey 08858. The application has been assigned to Johnson & Johnson Consumer Companies, Inc. by the inventors, Miri Seiberg, Stanley Shapiro and Jue-Chen Liu.

II. Related Appeals and Interferences:

There are no appeals or interferences known to Appellant or Appellant's legal representative which will directly affect or be directly affected by or have a bearing on the Board's decision in this present appeal.

III. Status of Claims:

Claims 1 to 22 are pending and are the subject of the present appeal. Claims 23-52 were withdrawn. Claims 1-22 were finally rejected under 35 U.S.C. §102(b), in an Office Action mailed May 21, 2002. Claims 1-22 were finally rejected under 35 U.S.C. § 103(a), in an Office Action mailed May 21, 2002.

IV. Status of Amendments:

An amendment (adding new claims 53 to 67) was filed subsequent to the Final Rejection, but the Examiner has denied the Amendment entry because, as indicated by the Examiner in the Advisory Action mailed August 12, 2002, the claims "are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or they present additional claims without canceling a corresponding number of finally rejected claims." Therefore, unentered new claims 53 to 67 are not the subject of this appeal.

V. Summary of the Invention:

As recited in claim 1, the present invention is directed to a method for effecting changes in mammalian hair appearance and hair pigmentation, and reducing hair growth, hair follicle and hair shaft size, comprising topical application to the skin of a mammal an effective amount of a topically active composition comprising one or more compounds derived from one or more of the botanical families leguminosae, solanaceae, gramineae and cucurbitaceae.

As discussed in the specification, the topically active composition described in the claims has retained serine protease inhibitory activity and the protein STI remains intact in the composition.

VI. Issues:

ISSUE 1

Whether claims 1 to 22 are anticipated by Kose Corp. (JP 5-25027).

ISSUE 2

Whether claims 1 to 22 are obvious over Kose Corp. (JP 5-25027) or Styczynski et al. (US 5,958,946).

VII. Grouping of Claims:

With respect to the rejections under 35 U.S.C. § 102 and 103, there is one group of claims. The group consists of independent claim 1 and dependent claims 2 to 22. Claims 1 to 22 do not stand or fall together.

VIII. Argument:

CLAIMS 1 TO 22 DO NOT STAND OR FALL TOGETHER

Claims 1 to 22 do not stand or fall together because claims of the group are separately patentable. Claim 1 is directed to effecting changes in mammalian hair appearance, pigmentation, hair growth, hair follicle size, and hair shaft size. However, claims 18 and 19 are separately patentable.

Claim 18 is directed to the prevention of or reduction of pseudofolliculitis barbae. Pseudofolliculitis barbae occurs mainly on the face, and deals with ingrown hair. This disorder, most often seen in men of African descent, results from close shaving of very curly hair, when the hair tips reenter the skin adjacent to the follicle producing the ingrown hair. Papules and pustules often result. It is unexpected that the present invention would work on this disorder, i.e. ingrown hair and papules and pustules. Claim 18 is, therefore, separately patentable.

Claim 22 is directed to the treatment of hirsutism. Most often seen in women, hirsutism is abnormal hairiness, which is especially seen in an adult male pattern (e.g. facial hair). This disorder does not result in papules or pustules but merely excessive hair. Hirsutism is a very different disorder from pseudofolliculitis barbae, and it is unexpected that the present invention would treat this disorder, i.e., effecting the amount of hair. Therefore, claim 22 is separately patentable.

Claim 19 is directed to reducing hair growth in the axillary area. Since the axillary area is not the face, and hair on the face and in the armpit often behave differently. As is noted in the arguments below, androgen sensitive and androgen insensitive hair both unexpectedly respond to this treatment and therefore, this claim is separately patentable.

ISSUE 1

Whether claims 1 to 22 are anticipated by Kose Corp. (JP 5-25027).

The present invention, described above and set forth in claims 1 to 22, is not anticipated over Kose Corp. (JP 5-25027) ("Kose").

The present invention requires an extract in which "the serine protease inhibitory activity ...will be retained," and "preferably that the protein STI will remain intact." These elements are not taught or disclosed by Kose for the reasons set forth below.

Appellants' invention comprises using a topically active composition derived from the leguminosae, solanaceae, gramineae, or cucurbitaceae families. The Examiner rejected claims 1-22 as being anticipated by Kose Corp. (JP 5-25027) ("Kose"). According to the examiner, Kose allegedly "reads on the topical application of an extract of the cucurbitaceae family, useful as a hair growth inhibitor[; and] that said extract inherently contains serine protease inhibitors and isoflavones[.]" Appellant traverses this rejection for the following reasons.

Kose's use of heat and non-polar, hydrophobic solvents results in either: (1) failure to extract the STI or (2) destruction of the STI activity. It is known in protein biochemistry that the conformation of protein, such as those in the present invention, namely their native tertiary and quaternary structures, are important to their activities. The conformation of proteins is largely dependent on weak bonds, which are very sensitive to changes, notably, the hydrophobic R groups of the amino acids of proteins tend to be close to each other at the interior of the folded protein, in order to be as far away as possible from the aqueous environment of living cells. (See, e.g. Keton & Gould, eds., Biological Sciences, 4th ed., Chapter 3, p. 66-67 (1986) of record in the Response filed February 8, 2002 and attached as Exhibit A). Hydrophobic solvents (e.g. hexane, or 70 % v/v ethanol) will expose these groups, changing the proteins' native structure and resulting in loss of activity.

Appellant notes in the specification of the present invention that Kose teaches “extracting solvents” in paragraph [0008] which are non-polar, and hydrophobic, which causes loss in activity of the proteins. Kose teaches heat in the extraction, which causes protein denaturation. However, once proteins are denatured, they are no longer biologically active. *See, Biological Sciences*, p. 66. Therefore, the extracting solvents and the heat will undoubtedly destroy STI’s activity (and this activity is important to the present invention).

Additionally, non-polar, hydrophobic solvents do not extract the STI, which are necessary for the present invention. Given that hydrogen bonds are weaker than the covalent bonds of the polypeptides, and the atoms in a protein that are hydrogen-bonded to each other could as easily be hydrogen-bonded to water, the proteins could be solubilized in water, but not organic solvents. (*See Doolittle, The Molecules of Life, Scientific American*, p. 42 (1985) of record in the Response filed February 8, 2002 and attached as Exhibit B). This clearly leads to the conclusion that the Kose extracting solvents cannot extract STI from any mixture.

In Appellant’s test of different solvents for extracting the STI, trypsin inhibition is greatly decreased with an increase in ethanol in an ethanol/water mixture. (Seiberg Declaration, ¶2 and Exhibit 2, of record in the Response filed February 8, 2002 and attached as Exhibit C). Kose’s use of “75 weight parts of the 70% v/v/% ethyl alcohol” has too low polarity to extract STI and too much alcohol, which will denature the compound. Therefore, Kose does not teach a topically active composition of the claimed invention.

Therefore, Kose does not teach or disclose the STI and that the STI activity remain intact. The Examiners’ rejection of claims 1 to 22 under 35 U.S.C. § 102(b) are traversed and appellant respectfully requests that this rejection be removed.

ISSUE 2

Whether claims 1 to 22 are obvious over Kose Corp. (JP 5-25027) or Styczynski et al. (US 5,958,946).

The present invention, described above and set forth in claims 1 to 22, is not obvious over Kose or Styczynski et al. (US 5,958,946) ("Styczynski").

Kose does not teach the present invention, and in fact teaches away from the present invention by using an excess of ethanol in extracting compounds from the cucurbitaceae family. An invention is not obvious in light of the prior art reference when the reference teaches away by leaving the impression that the invention would not have the properties sought by appellant. In re Caldwell, 319 F.2d 254, 256, 138 USPQ 243, 245 (CCPA 1963). "A reference that 'teaches away' cannot serve to create a *prima facie* case of obviousness." In re Gurley, 27 F. 3d 551, 553, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Appellant has tested different solvents for extracting the STI. Trypsin inhibition is greatly decreased with an increase in ethanol in an ethanol/water mixture. (Seiberg Declaration, ¶2 and Exhibit 2, of record in the Response filed February 8, 2002 and attached as Exhibit C). Thus, Kose's use of ethanol as an extraction solvent teaches away from the present invention as stated, for example, in paragraph [0014] as Kose's ethanol use would prevent sufficient trypsin inhibition. "75 weight-parts of the 70% v/v% ethyl alcohol" has too low polarity to extract the STI and too much alcohol, which will denature the compound. Again, Appellant respectfully asserts that this rejection regarding Kose should be withdrawn.

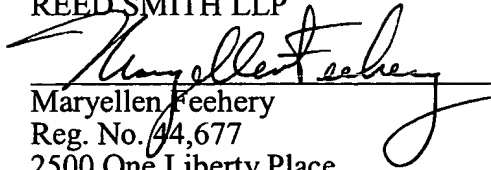
The Examiner additionally argues that Styczynski "teaches the topical application of an isoflavone to reduce hair growth [and] one of ordinary skill in the art would have expected an additive effect (i.e. reduction of hair growth) with the combination of one or more agents known to reduce hair growth." Styczynski teaches modulation of "hair growth by topical application of a compound that induces or activates the conjugation of an androgen." Col.2, line 8. Styczynski's invention, when used in a reduced hair growth area with androgens, will cause an increase in hair

growth. Appellant's invention is therefore very different from Styczynski's because the present invention will reduce hair in both types of areas (those which are androgen sensitive and non-androgen sensitive). Beard hair is androgen sensitive but leg hair is not androgen sensitive (*see*, Thornton, Effect of Androgens on the Growth of Cultured Human Dermal Papilla Cells Derived From Beard and Scalp Hair Follicles, J. Invest. Derm., 97:2, 345-8 (Aug. 1991) of record in Response filed February 8, 2002 and attached as Exhibit D), yet the present invention operates the same way in both, i.e., by reducing hair growth in both the leg and beard area (as opposed to inversely like Styczynski). Since Styczynski's invention actually has the opposite effect from the present invention, i.e. by promoting hair growth in beard hair (i.e., androgen sensitive hair), it clearly teaches away from Appellant's invention.

Further, the present invention is distinct from Styczynski's invention because, *inter alia*, unlike Styczynski, the present invention does not affect the hormone pathway. Styczynski's invention employs hormone pathways as described by the correlation of specific effects in androgen-stimulated areas and the opposite specific effects in androgen-reducing areas. Col. 2, lines 15-20. One of ordinary skill in the art would know that androgens and STI have different distinct pathways (Seiberg Declaration, ¶3, Exhibit C). STI do not affect the androgen pathway, unlike Styczynski's invention. Therefore, it would be nonobvious to one of ordinary skill in the art to use STI to effect hair growth as claimed in the Application.

In view of the foregoing discussion, it is respectfully submitted that the Examiner's rejections of claims 1 to 22 are improper and should be reversed by the Board.

Respectfully submitted,
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Elaine Byrnes
(Signature of person mailing paper or fee)

IX. APPENDIX

1. A method for effecting changes in mammalian hair appearance and hair pigmentation, and reducing hair growth, hair follicle and hair shaft size, comprising topical application to the skin of a mammal an effective amount of a topically active composition comprising one or more compounds derived from one or more of the botanical families leguminosae, solanaceae, gramineae and cucurbitaceae.
2. The method of claim 1 wherein said compound contains at least one serine protease inhibitory activity.
3. The method of claim 2 wherein said at least one serine protease inhibitory active agent is a serine protease inhibitor.
4. The method of claim 3 wherein said at least one serine protease inhibitor is present in an amount, based upon the total volume of the topically active composition, of from about 0.0001% (w/v) to 20%(w/v).
5. The method of claim 4 wherein the at least one serine protease inhibitor is present in an amount, based upon the total volume of the topically active composition, of from about 0.001% (w/v) to about 5% (w/v).
6. The method of claim 1 wherein one of said changes is a delay in hair growth, reduced hair follicle, hair shaft size and reduced hair pigmentation.
7. The method of claim 1 wherein said topically active composition further comprises a pharmaceutically or cosmetically acceptable vehicle.
8. The method of claim 1 wherein said topically active composition further comprises one or more isoflavones.
9. The method of claim 8 wherein said topically active composition further comprises a pharmaceutically or cosmetically acceptable vehicle.

10. The method of claim 1 wherein said topically active composition further comprises natural extracts containing one or more isoflavones.
11. The method of claim 1 wherein said composition is applied topically in conjunction with one or more products whose purpose is to either facilitate the removal of hair or actually remove hair or reduce hair visibility or improve hair style or improve hair management.
12. The method of claim 1 wherein said composition is applied topically before or following hair removal.
13. The method of claim 1 wherein said composition is applied topically during hair removal.
14. The method of claim 1 wherein said composition is applied topically in conjunction with one or more of the group consisting of: depilatory agents, shampoo, hair conditioner, styling gel, hair care products, waxing products, shaving products, hair-removal products, after-shave products, deodorant, anti-perspirant, electrolysis, laser hair removal, light-induced hair removal, mask, bath additives.
15. The method of claim 1 further comprising leaving said composition on said skin for a period sufficient to effect said changes.
16. The method of claim 1 wherein said period is daily treatment for at least about four weeks.
17. A method according to claim 16 wherein said composition is applied daily for at least eight weeks.
18. A method according to claim 1 wherein said composition is applied daily to reduce or prevent pseudofolliculitis barbae.
19. A method according to claim 1 wherein said composition is applied daily to the axillary area to reduce hair growth.

20. A method according to claim 1 wherein said composition is applied daily to the scalp to style and improve management of African type hair.
21. A method according to claim 1 wherein said composition is added daily to a bath.
22. A method according to claim 1 wherein said composition is used daily on facial or body parts for delaying hair growth and reducing hair visibility in sufferers of hirsutism.